

Message

From: Bussard, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CF26B876393E44F38BDD06DB02DBBFE5-BUSSARD, DAVID]
Sent: 10/12/2017 7:32:29 PM
To: Lavoie, Emma [Lavoie.Emma@epa.gov]
Subject: RE: TSCA and externally-done risk assessments

I'm trying to figure out how this might work if industry requests an assessment of some formaldehyde uses and provides a draft assessment. Does that mean Nancy then ignores the IRIS effort and OCSP does their own assessment building on the draft assessment from a manufacturer?

I don't think there is any legal reason IRIS could not still move forward, but it could be part of an Administration decision that an IRIS assessment independent of the submitted draft "is not needed".

From: Lavoie, Emma
Sent: Thursday, October 12, 2017 2:05 PM
To: Bussard, David <Bussard.David@epa.gov>; Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Subject: RE: TSCA and externally-done risk assessments

I'll note that if an outside evaluation is submitted, OPPT hardly has the resources to actually review it....so if the only timeline identified is the 3 years timeline in the section 6 risk eval section, then maybe they have 3 years to review it?!

-Emma

Emma T. Lavoie, PhD
Tel: 703-347-0328

From: Bussard, David
Sent: Thursday, October 12, 2017 12:16 PM
To: Lavoie, Emma <Lavoie.Emma@epa.gov>; Ramasamy, Santhini <Ramasamy.Santhini@epa.gov>
Subject: TSCA and externally-done risk assessments

STATUTE

The only statutory mention of externally-done risk assessments I can find is in Section 26 (l)(5):

(5) GUIDANCE.—Not later than 1 year after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator. [p. 74 of the statutory text Gino sent.]

GUIDANCE and RULE TEXT

The guidance says that in order for a draft assessment to be used in whole or in part by EPA, it will be most useful if it meets the requirements EPA assessments need to meet. It does not need to be peer reviewed – in that if EPA uses it in its draft assessment it will then undergo peer review as EPA presents its draft.

RE FORMALDEHYDE,

I also note that the TSCA rule on risk assessments does not legally apply to risk assessments initiated in support of other statutes or programs.

David A. Bussard

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